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Kateterburna mikrokirurgiska verktygsset

Sammandrag

Användningen av mikrokirurgiska verktygsset, burna på nålar i katetrar, med ett flertal elektriskt drivna mikroverktyg baserade på konjjugerade polymerers volymsförändring vid elektrokemisk stimulering.
Mikroverktyg kan användas för att hålla strukturer(clips), begränsa flöden genom cylindriska strukturer(clips, pincetter,), förstärka ihåliga cylindrar(stents), expandera strukturer, montera hållare genom membran, hålla cylindriska objekt för elektrisk kontaktering,

The use of microstructures to assemble, separate, fortify, close and hold biological structures inside the body during and after surgery

(stents, valves, clips, nets, knives, scissors, dilators, clamps, tweezers)

Introduction

The use of microstructures to assemble, fortify or dilate biological structures inside the body during and after surgery can help the surgeon in a number of ways. The operation of electrically actuated tools can relieve the surgeon of the simultaneous tasks of positioning the tool, operating it manually and observing the positioning and operation with some imaging method. By positioning the tool by hand and separately operating it through external control (i.e. footswitch, voice control, other software-control) a much higher degree of precision is expected. In microsurgery, this is an especially desired advantage.

Being able to apply, beforehand or during an invasive procedure, the tool of a required size and geometry - designed for the purpose of cutting, drilling, holding, dilating, suturing, adapting, supporting - from a set of tools that, for example, could be placed in the end of a catheter or needle, is another desired function, requiring development of microactuators.

The application of a tool placed in or introduced through a catheter or needle is of particular interest at the application of structures which are to be left at the site after insertion, and which have to execute their function for some limited time duration. The first example here is that of clips for surgery, sub-millimeter to millimeter structures, which would be used to hold two separated biological structures joined, for example during a healing period (Fig.1) .
Another example is that of structures for controlling the flow through blood vessels. The simplest level is that of a clip used to prevent blood flow to a biological structure downstream in the blood flow. Such a clip, or series of clips, would be mounted and left to hold a firm grip on the blood vessel and thus to prevent the flow of blood. In Figure 2 is shown a series of structures suitable for constricting blood vessels.

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The third example is at a somewhat more complex level with structures built in a geometry where they could be used inside or outside tube-like structures, as so called stents to dilate a stenotic area or to internally or externally fortify the structure (Figure 1B). Stents are of particular interest since they are to be inserted inside the tube, then to be left there to expand a stenotic or to fortify an area of the tube-like structure.

Arrays of fingers could be used to hold cylindrical objects, such as nerves and nerve fibers, or blood vessels. With the help of microactuators holding the structures (Fig. 3), adjacent microstructures operating as neural sensing or activating electrodes, will enable the reading or stimulation of the nerves. This could be used for a synthetic neural connector, bridging a severed nerve or nerve fiber.

Elements with some temporary mechanical function could be inserted in membranes (Fig.4) Insertion devices of this kind could be used for mounting a hole through a membrane such as commonly used in ear surgery for pressure equilibration. Making these as microdevices will much decrease the effort and nuisance of the inserted devices.

Clips, stents, finger arrays and insertion devices, once applied, could be resorbable or permanent. They could express various degrees of stimulation of cell growth on its surfaces, various degrees of anti-thrombotic activity as well as different anti-biotic activities. They can also be carriers of various biochemical or biological components.

The necessary elements to acccomplish these functions are the electrochemically activated micromuscles, built by micromachining thin metal and polymer layers (Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Controlled Folding of Micron-size Structures", Science **268** (1995) pp.1735-1738). These actuators can be produced in sizes from micrometers to centimeters, and operate well in biological fluids such as blood plasma, blood, buffer and urine. They are therefore suitable tools for micro invasive surgery inside the body. The versatility of construction and the speed of response, as well as the force of these actuators render them as one of the best types of microactuators inside the body. An international patent covers one route of fabrication of such devices (patent A Elisabeth Smela, Olle Inganäs och Ingemar Lundström: "Methods for the fabrication of micromachined structures and micromachined structures manufactured using such methods ", Svensk patentansökan SE 9500849-6,10 mars, 1995 in succession also a PCT and international patent)

Prior art

The combination of microactuators and catheters are not well documented in the literature. A patent search reveals a few examples but none that describes the use of microactuators as tools housed inside a catheter; several examples of microactuators use to position a catheter are to be found in the following patents

US5771902: Micromachined actuators/sensors for intratubular positioning/steering

US5819749: Microvalve

WO9837816A1: MICROFABRICATED THERAPEUTIC ACTUATORS

WO9739688A2: METHOD AND APPARATUS FOR DELIVERY OF AN APPLIANCE IN A VESSEL

WO9739674A1: SPRING BASED MULTI-PURPOSE MEDICAL INSTRUMENT

US5855565: Cardiovascular mechanically expanding catheter
).

Several mechanism are suggested for the microactuators in these applications, found among shape memory alloys (also polymeric materials) and piezoelectric materials. The use of conjugated polymers in micromuscles is not documented for catheter tools. Our novelty and innovation therefore resides in the use of microactuators based on conjugated polymers being electrically operated and mounted on a catheter needle, to be positioned with the help of the catheter, and then activating the microactuator structures carried on the needle. The microfabrication of such microactuators renders possible a number of geometries in the range between 10 µm to 1 mm, difficult to produce by mechanical production techniques. They may be produced by patent A above and then mounted on the needle, or they might be produced by novel manufacturing methods. With the help of this invention, completely novel microsurgery tools are available.

The production of individually actuated tool arrays render little difficulty beyond that of producing the individual tool; we have to see that electrical contacts are supplied to actuate each microactuator separately. This can be done by wiring the single microactuator, to be used as the working electrode; the catheter is then used as the counterelectrode, and will be able to supply all the charge we ever need to actuate all those microactuators. As wires may easily be produced in width down to 10 µm with photolithography or with soft lithography, we will be able to put at least 50 microactuators along the tool array located on a needle of 1 mm width, with the simple philosophy of putting down parallel conductor wires. Should we need more, more elaborate adressing schemes might be needed.
Should a necessity for three electrode systems be found in any of the applications, microfabricated reference electrodes or macrosize reference electrodes carried on the catheter housing offers a solution for this problem.

Should the tool arrays be collectively adressed, and the tool array be designed to set free the outermost clip on actuation of all the clips, we will need a mechanism of confining the movements of all but the outermost clip. This is done by assembling the clip array into a cylindrical housing, preferably the catheter, prior to insertion in the body. The cylindrical housing is now confining the motion of microactuators, which search in vain to expand the strong metal casing on operation. When the outermost clip C1 is actuated, the clip is opened; likewise is the next-to-the outermost clip C2 partially free to move as it is protruding outside the cylindrical housing. Therefore the partial opening of C2 sets C1 free, as well as opens it up for subsequent spontaneous closing on the site to be clipped.

Figure captions

Figure 1 shows clips and clip arrays, where the clips are mounted in sequence, and area confined by a cylindrical housing, and where the activation of the outer most clip C1 , opening up the clip to join the open structure W1, and then being set free by the simultaneous operation of C2 , so as to be left at the structure W1, holding the structures together.

Figure 2 shows tubular tweezers, tweezers and knifes, based on microactuators. The indicated movement is driven by microactuators properly mounted and designed.

Figure 3 shows a neurqal connector, where a number of small fingers coil around a cylindrical nerve to make a tight hold the the nerve. Two separate nerves are here joined with the help of a common neural connector, which would be desired for accomplishing regrowth of the nerves. In addition, small electrodes can be fashioned along with the microfingers, and be used to sense or excite nerve signals.

Figure 4 An insertion device, for making a (semi)- permanent hole through a membrane. The device is housed in a catheter and is inserted through the membrane so as to make the device form a hole through the membrane.

CLAIMS

1. Tool arrays for biomedical surgery,
characterized in that
(i) the tools consist of layered polymer micromuscles arranged to induce geometrical changes and movements via an electrochemically induced change of volume in at least one polymer layer, and
(ii) the tool arrays are mounted on a carrier having the form of a needle being inserted into a catheter, which arrays can be electrically actuated via an external means to induce a mechanical movement to act upon biological structures.

2. Tool arrays according to claim 1, characterized in that the layered polymer consists of a single layered polymer.

3. Tool arrays according to claim 1, characterized in that the layered polymer consists of a bi-layered polymer.

4. Tool arrays according to claim 1, characterized in that the layered polymer consists of multilayered polymer and metal layers.

5. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to position a biological structure.

6. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to hold a biological structure.

7. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to cut a biological structure.

8. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to dilate a biological structure.

9. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to fortify a biological structure.

10. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to implant a biological structure.

11. Tool arrays according to one or more of claims 1-10 , characterized in that a number of identical tools are located on a tool array extending along the length of the catheter or needle, and wherein the actuation of a tool closest to the exit of the catheter is arranged to release a tool from the tool array and is arranged to leave it at the point of exit of the catheter in order to mount the tool at some biological structure inside a body.

12. Tool arrays according to claim 11, characterized in that a number of identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

13. Tool arrays according to claim 11, characterized in that a number of non-identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

14. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clip arranged to join biological tissues or tissue parts, and arranged to hold the said tissues or tissue parts to allow healing.

15. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is an expandable cylindrical object designed to be inserted, in a contracted state, into a biological tube, and arranged to become expanded to keep said tube in an expanded state.

16. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a scissor.

17. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a knife which is arranged on an actuator being arranged for linear and/or angular movement.

18. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a sharp needle which is arranged on an actuator being arranged for linear and/or angular movement.

19. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a dilator.

20. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clamp.

21. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a tweezer.

22. Tool arrays according to one or more of claims 1-21, characterized in that the polymer micromuscles are built of layers, of which at least one is a conjugated polymer.

23. Tool arrays according to claim 22, characterized in that the conjugated polymer is selected from the group consisting of pyrrole, aniline, thiophene, para-phenylene, vinylene, and phenylene polymers and copolymers.

24. Tool arrays according to claim 1, characterized in that the tool is built of bi-layered polymer, where the electrically activated volume change of said at least one conjugated polymer is arranged to cause a bending of said bi-layer.

25. Tool arrays according to claim 1, characterized in that the tool is built of multilayered polymer, where the electrically activated volume change of said at least one conjugated polymer is arranged to cause a bending of said multilayer.

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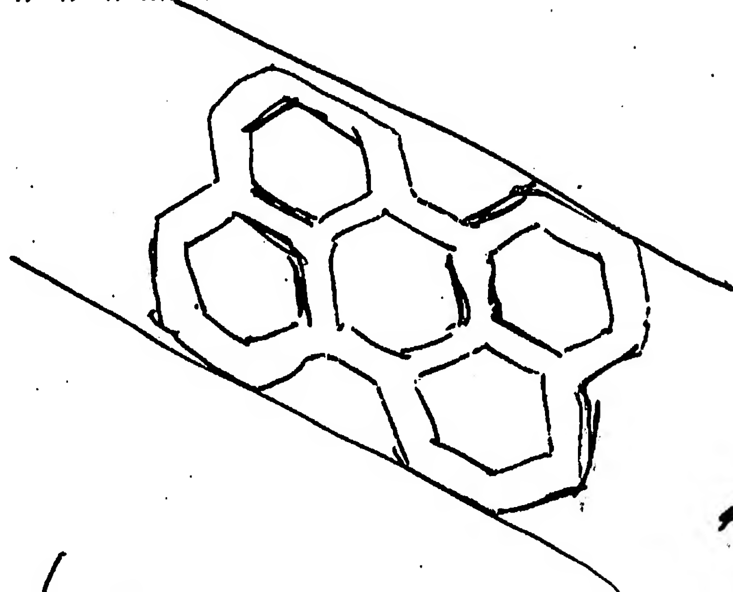
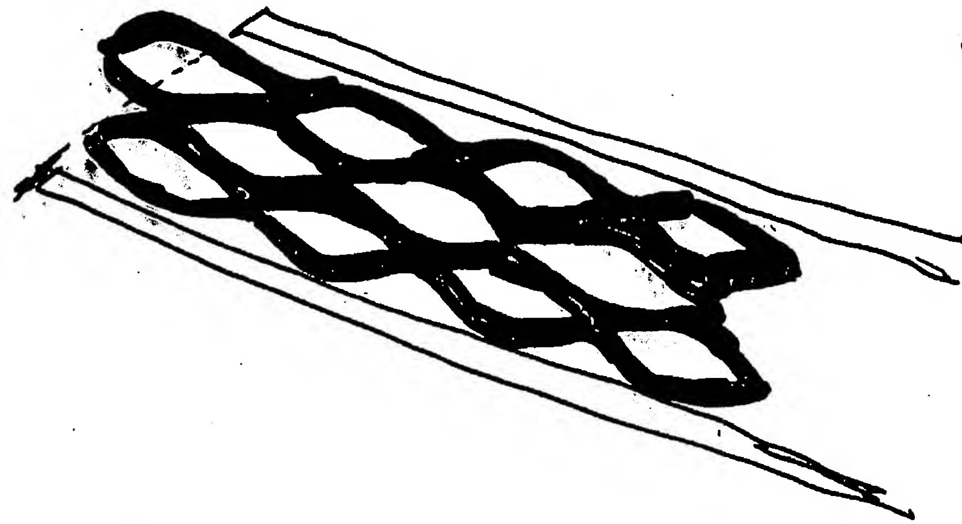
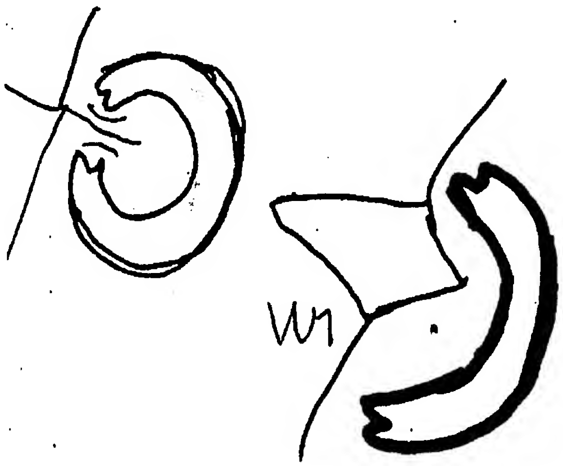
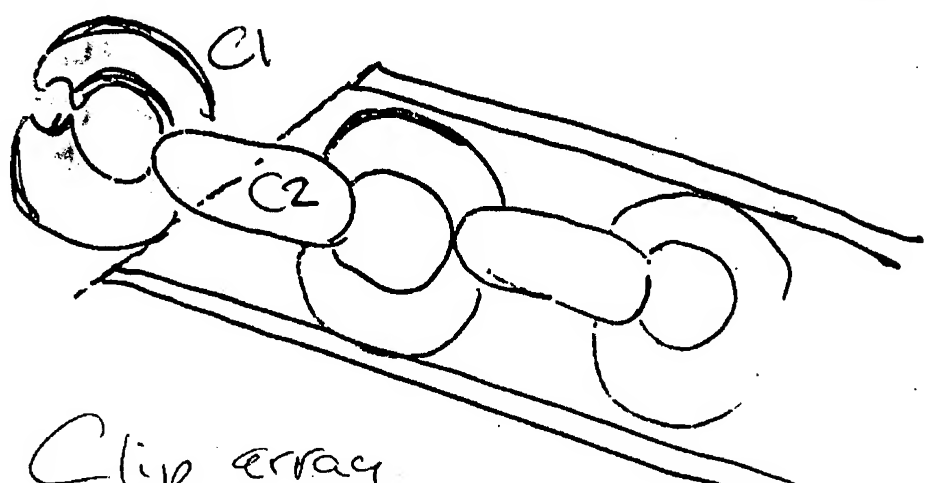


Fig 1B
Stent





Clip



Clip array

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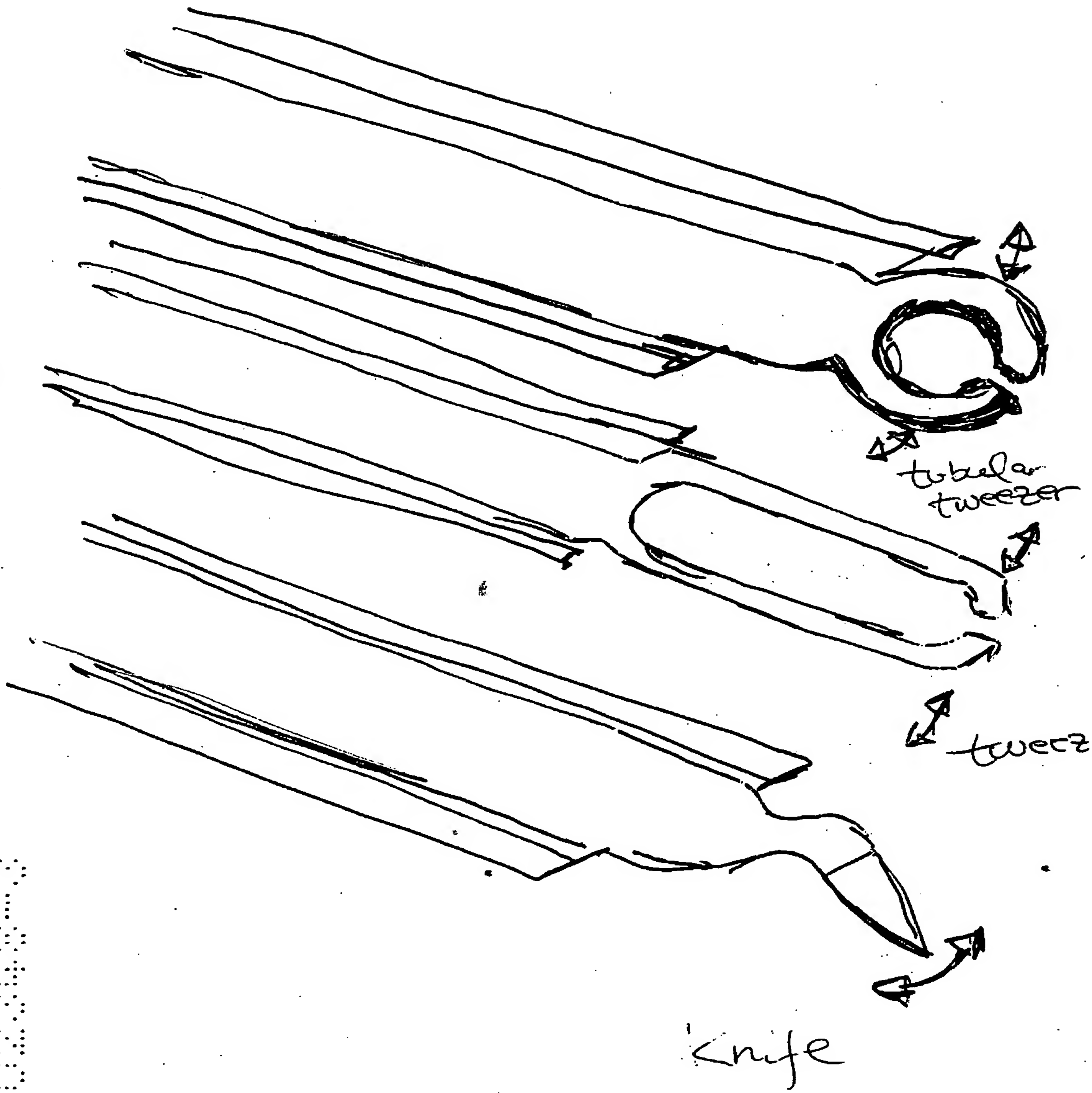
tubular tweezer
tweez
knife

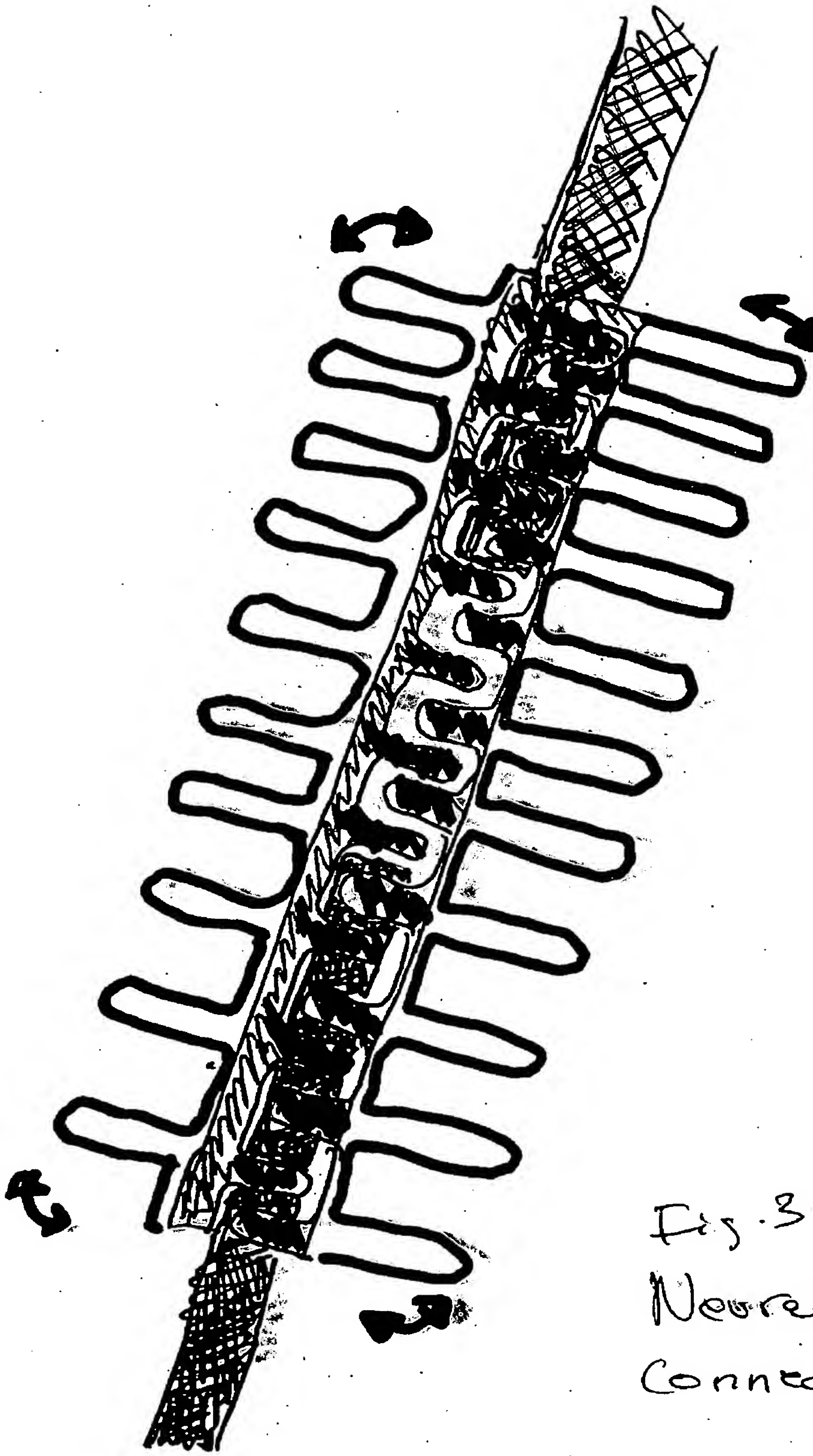

Fig. 3
Neural
Connector

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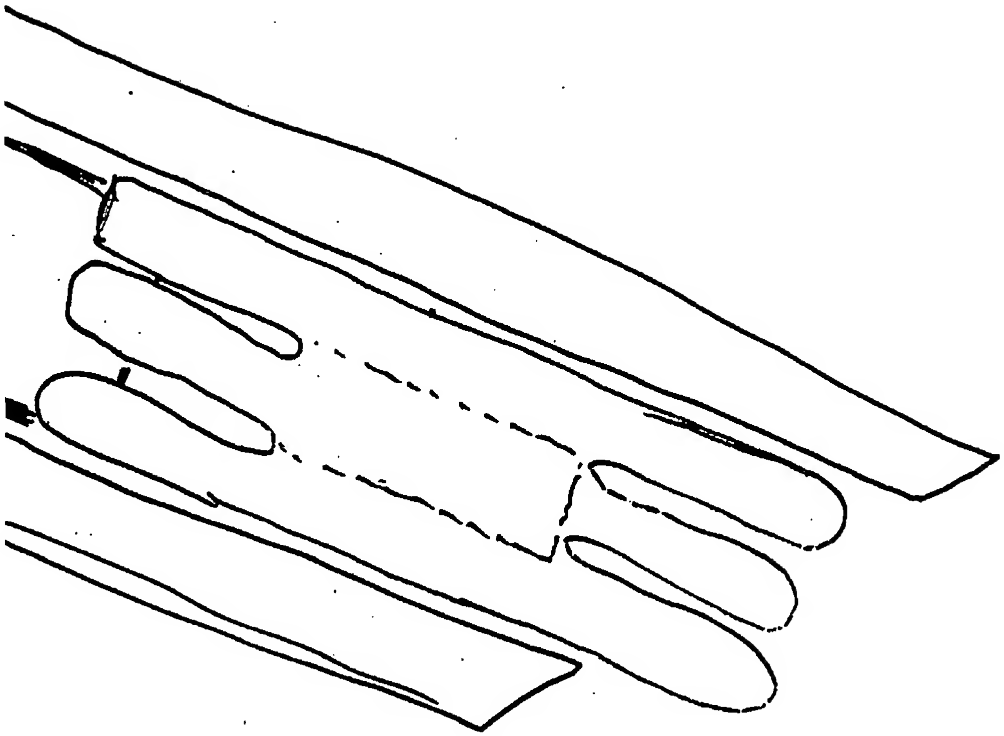
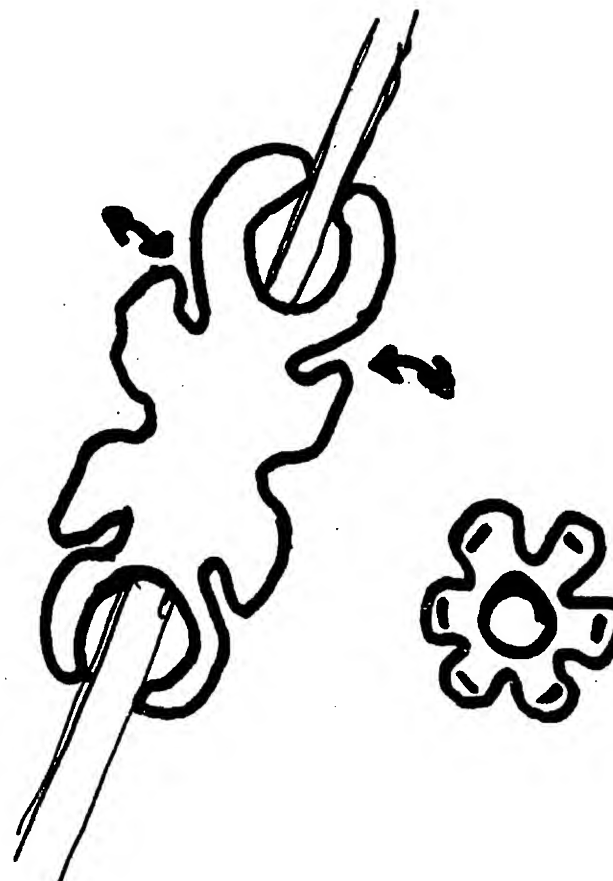


Insertion device



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